

**Remarks/Arguments:**

Page 1 of the Office Action of November 1, 2005 states that claims 1-32 are pending, and claims 21-31 have been withdrawn from consideration as drawn to a non-elected invention. Page 2 of the same Office Action states, inconsistently with page 1, and erroneously, that "[c]laims 1, 20 and 32 and claims 21-31 remain withdrawn . . . ." Applicants submit that claims 1-20 and 32 are under examination while claims 21-31 have been withdrawn. Clarification is requested.

***Claim rejections under 35 U.S.C. §102***

Claims 1-4, 7, 9-13, 20, and 32 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent Application Publication No. 2002/0095205 to Edwin et al. Of these claims, claims 1, 20 and 32 are independent.

Amended claim 1 recites, *inter alia*, a stent comprising a tubular expandable framework having an outer surface and an inner surface and a plurality of interconnected struts. The struts comprise a plurality of serpentine bands and further comprise a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough. The stent further comprises an outer covering of PTFE and an inner covering of PTFE. The outer covering extends along at least a portion of the outer surface of the expandable framework. The inner covering extends along at least a portion of the inner surface of the expandable framework. At least a portion of the inner and outer coverings are contiguous. The stent further comprises at least one radiopaque marker disposed between the inner covering and the outer covering. The radiopaque marker is attached to the connector strut.

Amended claim 20 recites, *inter alia*, a stent comprising a tubular framework having an outer surface and an inner surface and a plurality of interconnected struts, the struts comprising a plurality of serpentine bands and further comprising a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough. The stent further comprises an outer covering of PTFE and an inner covering of PTFE. The outer cover extends along at least a portion of the outer surface of the framework. At least a portion of the inner and outer coverings are contiguous. The connector strut has at least one marker which is radiopaque or which may be visualized using magnetic resonance imaging. The marker is disposed between the inner covering and the outer covering.

Amended claim 32 recites, *inter alia*, a covered stent comprising a stent framework having an interior surface, an exterior surface and a marker region. The framework comprises a plurality of serpentine bands and further comprises a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough. At least one radiopaque marker is located within the marker region of said framework. The marker is attached to the connector strut. A covering of expanded PTFE covers the interior surface and exterior surface of said framework in the marker region.

In order to anticipate a claim under 35 U.S.C. §102, the reference must teach every element of the claim. M.P.E.P. §2131. Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) and M.P.E.P. §2131.

Edwin fails to disclose or suggest any connector struts, let alone linear connector struts, as are recited in each of amended claims 1, 20, and 32. None of Edwin's stents 34, 54, or 74 are shown or described with any detail regarding any connector struts. Further, since Edwin fails to disclose or suggest any connector struts, it is axiomatic that Edwin also fails to disclose or suggest a radiopaque marker attached to the connector strut, as is also recited in each of claims 1, 20, and 32.

For at least the above reasons, Applicants respectfully submit that claims 1, 20, and 32 are patentable over the cited prior art and respectfully request reconsideration and allowance of claims 1, 20, and 32. Claims 2-4, 7, and 9-13 all depend, either directly or indirectly, from claim 1, and Applicants respectfully submit that these claims are allowable over the cited prior art for at least the same reasons as set forth above with respect to claim 1. Reconsideration and allowance of claims 2-4, 7, and 9-13 is respectfully requested.

***Claim rejections under 35 U.S.C. §103***

Claims 1-20 and 32 stand rejected under 35 U.S.C. §103(a) as unpatentable over Edwin in view of any of U.S. Patent Application Publication No. 2002/0044399 to Ventura ("Ventura"), U.S. Patent Application Publication No. 2003/0069630 to Burgermeister et al. ("Burgermeister"), and U.S. Patent Application Publication No. 2002/0193867 to Gladdish, Jr. et al. ("Gladdish"), and further in view of any of U.S. Patent No. 6,203,568 to Lombardi et al. ("Lombardi I"), U.S. Patent Application Publication No. 2004/0015228 to Lombardi et al.

("Lombardi II"), U.S. Patent No. 6,635,082 to Hossainy et al. ("Hossainy"), or U.S. Patent Application Publication No. 2002/0103528 to Schaldach et al. ("Schaldach").

Independent claims 1, 20, and 32 are discussed above. Edwin's shortcomings are also discussed above.

Ventura fails to disclose or suggest connecting the peak of one element with the trough of an adjacent element, as is recited in each of independent claims 1, 20, and 32.

Burgermeister fails to disclose or suggest a stent that has a series of strut sections that are connected by a series of generally linear connector struts, as is recited in each of independent claims 1, 20, and 32.

Burgermeister only discloses an expandable stent, and does not disclose or suggest any inner or outer covering. Further, Burgermeister's connecting struts are generally serpentine in shape and do not linearly connect a serpentine band with an adjacent serpentine band. When Burgermeister's stent is expanded, the serpentine nature of the connecting struts allows offset movement of one serpentine band relative to an adjacent serpentine band. Additionally, the serpentine connecting struts allow for linear expansion of the stent. The generally linear connector strut recited in each of independent claims 1, 20, and 32, on the other hand, precludes linear expansion of the stent and provides resistance to linear compression of the tubular member with no offset to that linear resistance.

Gladdish fails to disclose or suggest a stent that includes a plurality of serpentine bands that are connected to each other by connector struts that extend from the apex of the peak to the apex of the adjacent trough, as is recited in each of independent claims 1, 20, and 32. Rather, Gladdish's connectors connect non-adjacent serpentine bands at points that are slightly offset from apices of those bands. Also, Gladdish fails to disclose or suggest radiopaque markers that extend on any of the connector struts, as is also recited in each of claims 1, 20, and 32. Additionally, Gladdish only discloses an expandable stent, and does not disclose or suggest any inner or outer covering. Gladdish's connecting struts do not linearly connect each serpentine band with its adjacent serpentine band. Gladdish's connecting struts are also slightly serpentine in shape, such that, when Gladdish's stent is expanded, adjacent serpentine bands may rotate with respect to each other and linearly expand. As discussed above with respect to Burgermeister, the generally linear connector strut recited in each of independent claims 1, 20, and 32, on the other hand, precludes linear expansion of the stent.

Also, the configurations of the connecting struts of Burgermeister and Gladdish both allow for longitudinal compression of their respective stents. Each of claims 1, 20, and 32, on the other hand, recite generally linear connector struts that extend from the apex of the peak of one serpentine band to the apex of the adjacent trough of an adjacent serpentine band. Such claimed structure resists longitudinal compression of the stent.

Lombardi I, Lombardi II, Hossainy, and Schaldach are all cited for various methods used to place markers on a stent system. These references fail to disclose or suggest the limitation of a framework comprises a plurality of serpentine bands having a generally linear connector strut attaching a peak of one serpentine band to a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough, as is recited in each of amended claims 1, 20, and 32.

Even if one were to combine any of Ventura, Burgermeister, and Gladdish with Edwin, the claimed feature of a generally linear connector strut connecting the peak of one serpentine band with a trough of an adjacent serpentine band at the respective apices of each of the peak and the trough is neither disclosed nor suggested by any of the prior art. As discussed above, Edwin fails to disclose any connector struts whatsoever. Ventura discloses connector struts 20 that connect the peak of one band with the peak of an adjacent band or the trough of one band with the trough of an adjacent band, but not the peak of one band with the trough of an adjacent band. Burgermeister discloses a generally serpentine connector strut that connects one band with an adjacent band. Burgermeister fails to disclose or suggest any generally linear struts. Gladdish discloses a connector strut 116 that connects adjacent bands, but away from the apices of the bands and troughs. Gladdish fails to disclose or suggest connecting the apices of either the trough or peak of one band with the apices of a peak or trough of an adjacent band. Since Lombardi I, Lombardi II, Hossainy, and Schaldach are all cited for various methods used to place markers on a stent system, Applicants respectfully submit that these references fail to cure any of the deficiencies discussed above and that the combination of Edwin with any of Ventura, Burgermeister, and Gladdish and further in view of any of Lombardi I, Lombardi II, Hossainy, and Schaldach fails to disclose or suggest the invention claimed in each of claims 1, 20, and 32.

Further, the cited art lacks any suggestion that the primary reference should be modified in a manner required to meet the claims. Edwin is a fully operational expandable stent that includes radiopaque markers to enable fluoroscopic examination of the location of the stent within a patient. Inner and outer bands of expandable PTFE cover the stent and the radiopaque

markers. There is no need for one having ordinary skill in the art, after reading Edwin, to look to any of the cited references in order to obtain an expandable stent having radiopaque markers and that includes inner and outer bands of expandable PTFE that also covers the markers. There is no disclosure or suggestion in Edwin to modify Edwin with connector struts in order to meet the claimed invention.

Also, in addition to Edwin not containing any suggestion to be modified with any of Ventura, Burgermeister, and Gladdish, Applicants respectfully submit that Edwin, as well as Ventura, Burgermeister, and Gladdish, are all individually complete in themselves, and none of the references require any modification to disclose an operational stent with radiopaque markers. All of Edwin, Ventura, Burgermeister, and Gladdish disclose fully operational expandable stents with radiopaque markers to help a physician determine the location of the stent within a patient. Since all of the references disclose complete and fully functional stents, one skilled in the art would have no motivation to use parts from any of the references in order to make any of the other references complete and fully functional.

Further, even if one were to attempt to modify Edwin to arrive at the claimed invention, one would have to modify Edwin in a manner not taught in the prior art in order to arrive at the claimed invention. The claimed invention recites a plurality of serpentine bands, with a generally linear connector strut connecting the peak of one serpentine band with a trough of an adjacent serpentine band. Edwin is vague about his description of the stent and provides no suggestion as to its structure, other than that it is self-expanding. Paragraph [0020]. Since Edwin's disclosure fails to provide any definitive description of his stent design, one of ordinary skill in the art would not know how to modify Edwin to arrive at the claimed invention, including a plurality of serpentine bands, with a generally linear connector strut connecting the peak of one serpentine band with a trough of an adjacent serpentine band.

For at least the reasons set forth above, Applicants respectfully submit that the rejection of independent claims 1, 20, and 32 is improper. Applicants respectfully request reconsideration and allowance of the claims. Claims 2-19 all depend, either directly or indirectly, from claim 1, and Applicant respectfully submits that claims 2-19 are patentable over the cited art for at least the same reasons as those presented above for claim 1.

New claims 33-39 are presented as alternative ways of defining Applicants' invention and are also patentably distinguishable from the known prior art.



**Conclusion**

With the present amendments and arguments, Applicants respectfully submit that the present application is in condition for allowance. Prompt reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

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